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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,657	09/08/2003	Emil W. Ciurczak	206.1004US	2181

7590

10/04/2004

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,657	CIURCZAK ET AL.	
	Examiner	Art Unit	
	Eric F Winakur	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 20-33, 35-72, 74, 78 and 80-82 is/are rejected.
- 7) ☒ Claim(s) 18, 19, 34, 73, 75-77 and 79 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2 - 4, 13, 28, 38 - 41, 50, 51, 55 - 58, 60 - 65, 70, 80, and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard to claims 2, 3, 28, 38, 39, 50, 51, 55 - 58, 60, and 65, the phrase "the central processing device" is inconsistent with its antecedent. With regard to claim 13, the phrase "the filtering means" lacks antecedent basis. With regard to claim 58, the term "confiigured" should read "configured". With regard to claim 70, it appears that the claim should depend from claim 69 to provide proper basis for the phrase "the infrared spectrometer". With regard to claim 80, although "pulse rate" and "blood pressure" are physiological values related to blood they are not considered to be "constituents"; thus their inclusion in the Markush group seems improper.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 10, 11, 13, and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims improperly define the device in relation to a part of a living being (body part). Applicant should claim that the

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various elements are "adapted to be" in their particular relation to the body part to avoid positively claiming the body part.

Double Patenting

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6. Claim 66 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 55. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 55, 66, 74, and 78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13, 21, and 23 of U.S. Patent No. 6,675,030. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are broader than those of the patent (blood constituent is recited in the application where blood glucose is recited in the patent). Thus, any method or system meeting the limitations of the patent would necessarily meet those of the application.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1 - 3, 5, 7 - 10, 26, 28 - 30, 32, 35 - 41, 49 - 54, 56, 57, 59, 67, and 69 - 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Böcker et al. (USPN 5,507,288 - cited by Applicant). Böcker et al. disclose a glucose monitoring device that performs optical non-invasive spectral measurements and invasive glucose measurements. A processor uses both inputs to calibrate the non-invasive sensor. Particular attention is drawn to Figure 2 and the description thereof in columns 5 - 7. Column 3, lines 8 - 26 provide general requirements for the optical measurement system.

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11. Claims 1 and 80 - 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida. Yoshida teaches an arrangement to measure constituents, including cholesterol, which includes performing optical measurements with goggles that can wirelessly transmit data to an external data processor (column 4, lines 21 - 30). The data processing relies on calibration and analytical values (column 6, lines 1 - 56) which inherently requires invasively obtained data.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al. as applied to claims 3 and 5 above, and further in view of Heinonen et al. (USPN 5,840,020 - cited by Applicant). With regard to claim 4, Böcker et al. teach a device having the invasive device incorporated with the processing device. Heinonen et al. teach that these elements can be arranged having a mobile phone link between them (column 4, lines 4 - 21; Figure 1). With regard to claim 6 it is noted that Böcker et al. teach several wireless telemetry methods (column 4, lines 14 - 17), but do not particularly teach use of the data links recited in the claim. Heinonen et al. disclose an alternate telemetry method (mobile phone/cellular data link) that is suitable for use in medical telemetry. It would have been obvious to one of ordinary skill in the art at the

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time of the invention to substitute the arrangement of Heinonen et al. in the device of Böcker et al. for transfer of the data between the invasive sensor and the processor and to use a cellular link for the wireless link disclosed in Böcker et al. since it has generally been held to be within the skill level of the art to substitute alternate equivalent arrangements of elements.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al. as applied to claim 9 above, and further in view of Rosenthal (USPN 5,068,536 - cited by Applicant). Böcker et al. teach a reflection based measurement arrangement. Rosenthal teaches an alternate glucose measurement device that uses a transmission arrangement. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Böcker et al. to use a transmission arrangement, as taught by Rosenthal, since this is merely an alternate non-invasive optical measurement arrangement and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

15. Claims 12 - 14, 20 - 27, 31, 33, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al. as applied to claims 9, 30, and 32 above, and further in view of Caro (USPN 5,348,003 - cited by Applicant). Böcker et al. disclose general details on the optical measurement device suitable for use in their system (column 3, lines 8 - 26), but do not teach the particular details as provided in the claims. However, Caro discloses that these are merely well known arrangements of standard spectrometer systems. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the optical measuring device of Böcker et al. with

the arrangements of Caro, since Böcker et al. require an optical measurement system and Caro discloses such a system.

16. Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al. as applied to claim 67 above, and further in view of Steil et al. Böcker et al. teach all of the features of the claimed invention except that the device controls administration of a drug to a patient. Steil et al. teach a closed loop insulin infusion system that relies on output from a blood glucose sensor system for input to an insulin delivery system. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Böcker et al. to include control of administration of a drug, as taught by Steil et al., since this provides for greater control of blood glucose levels in diabetic patients.

17. Claims 42, and 46 - 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al. as applied to claim 1 above, and further in view of Eppstein et al. (USPN 6,045,502 - cited by Applicant). Böcker et al. teach that standard optical measurement arrangements can be incorporated in their device, but do not particularly teach an arrangement including a linear variable filter. Eppstein et al. teach an optical measurement arrangement incorporating a linear variable filter (column 5, lines 6 - 21). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Böcker et al. with the arrangement of Eppstein et al., since Böcker et al. require an optical measurement system and Eppstein et al. teach one such arrangement.

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18. Claims 15 - 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Böcker et al. and Caro as applied to claim 12 above, and further in view of Eppstein et al. The combination teaches several standard optical measurement arrangements but does not particularly teach an arrangement including a linear variable filter. Eppstein et al. teach an optical measurement arrangement incorporating a linear variable filter (column 5, lines 6 - 21). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the combination with the arrangement of Eppstein et al., since the combination requires an optical measurement system and Eppstein et al. teach one such arrangement.

19. Claims 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Böcker et al. and Caro as applied to claim 43 above, and further in view of Fein (USPN 5,243,465 - cited by Applicant). The combination does not disclose the particular material of the prism light guide. Fein (column 4, lines 53 - 66) teaches standard materials for making prisms, including fused silica. It would have been obvious to use a standard prism in the optical arrangement of the combination.

Allowable Subject Matter

20. The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest a system, as set forth in the claims, including a piezoelectric bimorph as a translation device, a plurality of optical fibers and switching device for delivering detected light to a detector, or the particular arrangements of claims 58, 60, 73, or 74.

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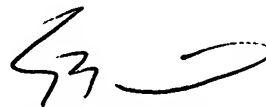
21. Claims 18, 19, 34, 73, 75 - 77, and 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. Claims 58 and 60 - 65 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 703/308-3940. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703/308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3736